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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,219

01/17/2006

Darren R. Shafren

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28213 7590 04/01/2008  
DLA PIPER US LLP  
4365 EXECUTIVE DRIVE  
SUITE 1100  
SAN DIEGO, CA 92121-2133

EXAMINER

LI, BAO Q

ART UNIT

PAPER NUMBER

1648

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/539,219	SHAFREN, DARREN R.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 8-35 and 43-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 36-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)                |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application      |
| Paper No(s)/Mail Date <u>6/15/2006</u> .   | 6) <input checked="" type="checkbox"/> Other: <u>Sequence letter</u> . |

### **DETAILED ACTION**

The preliminary amendment filed on Jan 17, 2008 has been respectfully considered; claims 1-62 have been amended. Claim 64 has been canceled.

#### ***Sequence requirements***

This application contains sequence disclosures in lines 1-3 of page 23 that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

#### ***Election/Restrictions***

1. Applicant's election of group I, claims 1-7 and 36-42 in the species of EV1 in the reply filed on Jan. 30, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

#### ***Specification***

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In the instant case, the specification does not have antecedent basis for the term of "abnormal cell" cited in the claims.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-7 and 36-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). In the instant case, the metes and bounds of cited abnormal cells are not defined. In the instant case, the claimed method is directed to treatment of cancer or tumor cells with echo virus. However, applicants seem to refer all cancer or tumor cells as abnormal cells. The term “abnormal cells” in claims 1-7 and 36-42 is used by the claim to mean “cancer or tumor cells” that express abundant  $\alpha\beta1$  integrin”, while the accepted meaning is “cancer and tumor or neoplastic cells.” The term is indefinite because the specification does not clearly redefine the term.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-7 and 36-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, Application does not provide description for using a modified echo virus or combination of the echo virus with modified form of echo virus thereof to treat an abnormal cells.

8. The first paragraph of 35 U.S.C. requires that the specification shall contain a written description of the invention. This requirement has several objectives: 1). To clearly convey the information that an applicant has invented the subject matter which is claimed; 2). To put the

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public in possession of what the applicant claims as the invention; and 3). To promote the progress of the useful arts by ensuring that patentee adequately describe their inventions in their patent specification in exchange for the right to exclude others from participating the invention for the duration of the patent term.

9. Therefore, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. The possession of claimed invention can be shown by describing the claimed invention with all of its limitations in the specification including drawing or description of an actual reduction to practice. The written description may arise in the following situations: a). The claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention; b). The claimed invention as a whole may not adequately be described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art; and c). The invention is described solely in terms of a method of its making coupled with its function and there is no described or art recognized correlation or relationship between the structure of the invention and its function etc.

10. In the instant case, the claimed invention has not described any modified echo virus or any method for making a modified echo virus as well as a method using such modified echo virus or in combination with wild type echovirus thereof to treat "abnormal cells".

11. While integrin  $\alpha 2/\beta 1$  subunits have been reported to be associated with echo virus 1 (EV1) entry target cells possibly via endocytosis. However, there is insufficient data available on the location of the neutralization epitopes in EV1 responsible for this entry (Xing L. Non-enveloped virus infection probed with host molecular molecules: A structural study, 2002, see page 36). Therefore, the person ordinary skilled in the art at the time of current Application would not be able to recognize what kind of modification should be made to enhance the virus entry. The person ordinary skilled in the art at the time of current would not be able to recognize that applicant has such modified echo virus and uses it to treat abnormal cells.

12. Therefore, in view of the guideline of the written description, the claimed method using a modified echo virus lacks 1). the structure of the modified echo virus; 2). Physical and/or

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chemical properties of such modified echo virus; and the relationship between the structure and the function; 3). Functional characteristics of such modified echo virus; 4). Method of making the modified echo virus. Therefore, the claims 1-7 and 36-42 are rejected for lack of written description to support the claimed invention.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 3, 36, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ferdat et al. (Eksp Onkol 1989, Vol. 11, No. 5, pp. 43-48, Abstract only).

15. Ferdat et al. teach a method for treating tumor using echo virus serotype 7 (echo-7) in mice. The treatment nevertheless causes tumor regression (See abstract). Because the method taught by Ferdat et al. contains the same active steps to the claimed method, claims 1, 3, 36-37 are anticipated by Ferdat et al.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao Qun Li/

Primary Examiner, Art Unit 1648

March 27, 2007.

<div>Application Number</div> <div></div>	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/539,219	SHAFREN, DARREN R.	
	Examiner	Art Unit	
	Bao Qun Li	1648	